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Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/556,060	Applicant(s) MEINKE ET AL.	
	Examiner Padmavathi v. Baskar	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38-60 is/are pending in the application.
- 4a) Of the above claim(s) 51 and 52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38-50, 53 and 54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/8/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's response to restriction requirement filed on 10/24/06 is acknowledged.

Election/Restriction

2. In response to the restriction requirement, Applicants elected, with traverse, to prosecute the "Group I invention," as exemplified by claims 38-44 and 45-54, SEQ.ID.NO:364 (gbs2018) drawn to a hyperimmune serum reactive hyper immune serum reactive antigen (*Streptococcus agalactiae*) and a pharmaceutical composition.

Applicant states that contrary to the statements of the restriction requirement, the claims do contain a common special technical feature. All of the claims relate to the common technical feature of "a hyperimmune serum-reactive hyper immune serum reactive antigen comprising an amino acid sequence from any of SEQ ID NO: 218-434, 449-462, or 475-486." This element is set forth specifically in claim 38, by reference to claim 38 in claim 45, and by reference to claim 45 (and thereby claim 38) in claim 55. Further, the cited reference of Stalhammar-Carlemalm et al does nothing to destroy novelty of this common technical feature, because it merely discloses an 95 kDa hyper immune serum reactive antigen fragment (protein Rib), which apparently exhibits no sequence identity or similarity to any of the claimed SEQ ID NO: 218-434, 449-462, or 475-486. In view of the above, the "Group I invention" and 25710458.1 "Group II invention" have a single inventive concept as required by PCT Rule 13:2, and Applicants request withdrawal of the restriction requirement and examination of all pending claims in the present case. Additionally, Applicants elect for further prosecution the amino acid sequence of SEQ ID NO: 364 (gbs 2018). Finally, with regard to the species election requirement, applicants elect the species of claim 50 wherein the immunostimulatory substance is a peptide containing at least two Lys Leu Lys motifs. Claims 38-50 and 53-60 are generic with regard to this species

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election, and Applicants reserve all rights under the rules to have any non-elected species within the scope of an allowed generic claim examined in this application in the future.

Applicant indicated that in view of this species election, Applicant elected SEQ.ID.NO:364, consideration of claims to additional species should no prior art be found relating to the elected species. It is noted however, that the restriction requirement was not drawn to election of species, but rather was drawn to an election of a specific group. As previously set forth,

The claimed inventions do not have unity of invention because the first invention first named does not define a contribution over the prior art and therefore, the invention does not have a special technical feature. The special technical feature shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. As previously set forth, Stalhammar-Carlemalm et al J.Exp.Med. 1993, 177, 1593-1603 disclose hyper immune (anti rabbit IgG) reactive hyper immune serum reactive antigen fragment 95kD (see abstract and figures 3, 4, 6 and 9). This reads on the claimed fragments thereof because "fragment of an amino acid sequence from any of SEQ ID NO: 218-434, 449-462, or 475-486 or fragments thereof" is viewed as hyper immune serum reactive antigen polypeptides comprising one or two amino acids of any sequence. Any and all hyperimmune serum reactive antigens would be expected to have at least one amino acid in common with the claimed sequence, therefore, 95 kd antigen meets the limitations of the claims "comprising" undefined fragments. In addition, Telford et al disclose an isolated hyper immune serum reactive antigen comprising an amino acid sequence SEQ.ID.NO:806 (i.e., fragment) and is 100% identical to the claimed an amino acid of SEQ.ID.NO: 364. Thus, as drawn to Telford et al, the issue remains the same. That is that the technical feature of linking groups I-II does not constitute a special technical feature as defined by PCT Rule 1:32, as it

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does not define a contribution over prior art and hence unity of invention is lacking. Therefore, only group I, claims 38-50, 53 and 54 with respect to SEQ.ID.NO:364 and immunostimulatory substance, a peptide containing at least two Lys-Leu-Lys motifs will be examined.

The requirement is still deemed proper and is therefore made FINAL. Applicant timely traversed the restriction (election) requirement in the reply filed on 10/24/06.

Status of claims

3. Claims 1-37 are cancelled.

Claims 38-60 are pending.

Claims 51-52 are withdrawn from the elected group I invention, as they are not drawn to the elected immunostimulatory substance, a peptide containing at least two Lys-Leu-Lys motifs.

Therefore, claims 38-50, 53 and 54 with respect to SEQ.ID.NO:364 and immunostimulatory substance, a peptide containing at least two Lys-Leu-Lys motifs are under examination. Applicant is advised to limit the claims to the elected invention, SEQ.ID.NO. 364.

Claims 55-60 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group of inventions M.P.E.P § 821.03.

Information Disclosure Statement

4. The Information Disclosure Statement filed on 11/8/06 is signed and a copy of the same is attached with this office action.

Claim Rejections - 35 USC 101

5. 35 U.S.C. 101 reads as Follows

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

6. Claims 38-44 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The product, hyperimmune serum reactive hyper immune serum reactive antigen as claimed, has the same characteristics as that found in nature

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because the protein can be obtained from *Streptococcus agalactiae* infected human body etc. To overcome this rejection the Examiner suggests the amendment of the claims to include purity limitations which would distinguish the characteristics and utility of applicant's product as enabled in the specification from the utility of the product as it exists in nature. It is further suggested that such limitation include the terminology " purified and isolated" (i.e. if such purity is supported in the specification) and/or a description of what applicant's protein is "free of" relative to the natural source which imparts a distinct utility to the claimed product. For relevant case law see Farbenfabriken of Elberfeld Co. v. Kuehmsted, 171 Fed. 887, 890 (N.D. Ill. 1909) (text of claim at 889); Parke-Davis & Co. v. H.D. Mulford Co., 189 Fed. 95, 103, 106, 965 (S.D.N.Y. 1911) (claim 1); and In re Bergstrom, 427 F.2d 1394, 1398, 1401-1402 (CCPA 1970).

Claim Rejections - 35 USC 112, first paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 38-50, 53 and 54 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is referred to the revised guidelines on written description available at www.uspto.gov (O.G. published January 30, 2001). This is a written description rejection.

Claims are drawn to a hyperimmune serum-reactive *S. agalactiae* hyper immune serum reactive antigen comprising an amino acid sequence of SEQ.ID.NO:364 or fragments thereof, said hyper immune serum reactive antigen or fragment comprising at least 6 or 8 or 10

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contiguous amino acids of SEQ.ID.NO:364, said hyper immune serum reactive antigen or fragment comprising an amino acid sequence of 8-36, 40-64 ----- 458-624 of SEQ ID NO. 364. Claims are drawn to a pharmaceutical composition comprising at least one hyper immune serum reactive antigen or fragment and optionally a pharmaceutically-acceptable carrier or excipient, said composition further comprising an immunostimulatory substance, wherein the immunostimulatory substance is a peptide containing at least two Lys-Leu-Lys motifs and said pharmaceutical composition is a vaccine.

The written description rejection is made because the claims are interpreted as drawn to a genus of products recited as "an amino acid sequence of 8-36, 40-64 ----- 458-624 of SEQ ID NO. 364 or fragments thereof". To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claims is an isolated hyper immune serum reactive hyper immune serum reactive antigen comprising the amino acid sequence of SEQ.ID.NO:364 structure/function of the product being claimed. There is not even identification of any particular portion of the structure that must be conserved in order to be "hyper immune serum reactive fragments".

The instant specification may provide an adequate written description for an isolated hyper-immune serum reactive hyper immune serum reactive antigen *S. agalactiae* comprising the amino acid sequence set forth as SEQ ID NO. 364 and is used together with an adjuvant for inducing a partial protective immune response. The specification fails to disclose isolated hyper immune serum reactive antigen comprising fragments thereof. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus "fragments thereof".

Although drawn to DNA arts, the findings in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and Enzo Biochem, Inc. V. Gen-Probe Inc. are relevant to the instant claims. The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that "[a] written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a

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precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Id.* At 1567, 43 USPQ2d at 1405. The court also stated that a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA" without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. *Id.* At 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.*

Finally, the court addressed the manner by which a genus of cDNAs might be described. "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." *Id.*

The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that "the written description requirement can be met by 'show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristicsi.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled

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with a known or disclosed correlation between function and structure, or some combination of such characteristics." Id. At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

The inventions at issue in Lilly and Enzo were DNA constructs per se, the holdings of those cases are also applicable. The instant specification may provide an adequate written description an isolated hyper immune serum reactive antigen SEQ.ID.NO:364, however, the specification fails to teach isolated serum reactive hyper immune serum reactive antigen comprising undefined fragments of SEQ.ID.NO:364. The specification fails to teach the structure or relevant identifying characteristics of a representative number of species of isolated hyper immune serum reactive antigen comprising undefined fragments of SEQ.ID.NO:364 as per Lilly by structurally describing a representative number of fragments or by describing "structural features common to the members of the genus, which features constitute a substantial portion of the genus" have to disclosed. In this application such structural features common to the isolated hyper immune serum reactive antigen comprising undefined fragments of SEQ.ID.NO:364 have not been disclosed. Alternatively, per Enzo, the specification can show that the claimed invention is complete "by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." In this case, the specification does not disclose isolated serum reactive hyper immune serum reactive antigen comprising undefined fragments of SEQ.ID.NO:364, required to practice the claims in a manner that satisfies either the Lilly or Enzo standards. The specification does not provide the complete structure of hyper immune serum reactive antigen comprising fragments nor does the specification provide any partial structure of such isolated serum reactive hyper immune serum reactive antigen comprising undefined fragments of SEQ.ID.NO:364, nor any physical or

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chemical characteristics of the isolated serum reactive hyper immune serum reactive antigen comprising undefined fragments of SEQ.ID.NO:364 nor any functional characteristics coupled with a known or disclosed hyper immune serum reactive antigen correlation between structure and function. Although the specification discloses an isolated hyper immune serum reactive antigen comprising the amino acid sequence SEQ.ID.NO:364 and does not provide a description of hyper immune serum reactive antigen comprising fragments that would satisfy the standard set out in Enzo.

The specification also fails to describe isolated serum reactive hyper immune serum reactive antigen comprising undefined fragments of SEQ.ID.NO:364 by the test set out in Lilly. The specification describes only protein comprising the amino acid sequence SEQ.ID.NO:364 that can be used as pharmaceutical composition against streptococcal infection caused by *Streptococcus agalactiae* using said hyper immune serum reactive antigen. Therefore, it necessarily fails to describe a "representative number" of such species, isolated serum reactive hyper immune serum reactive antigen comprising undefined fragments of SEQ.ID.NO:364. In addition, the specification also does not describe "structural features common to the members of the genus, which features constitute a substantial portion of the genus." Thus, the specification fails to teach the isolated serum reactive hyper immune serum reactive antigen comprising undefined fragments of SEQ.ID.NO:364 and does not satisfy the written description guidelines.

Thus the claims do not comply with 35 USC 112, first paragraph because they are not supported by an adequate written description in the specification.

9. Claims 38-50, 53 and 54 are also rejected under 35 U.S.C. 112, first paragraph, , because the specification, while being enabling for an isolated hyper immune serum reactive *S. agalactiae* antigen comprising the amino acid sequence SEQ.ID.NO: 364 or an hyper immune

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serum reactive antigenic fragment consisting of amino acids of 8-36, 40-64 ----- 458-624 of SEQ ID NO. 364 and a pharmaceutical composition comprising the amino acid sequence SEQ.ID.NO: 364 , pharmaceutically acceptable carrier does not reasonably provide enablement for a hyperimmune serum-reactive *S. agalactiae* antigen comprising fragment thereof , wherein the hyper immune serum reactive antigen comprises amino acids of 8-36, 40-64 ----- 458-624 of SEQ ID NO. 364 and a pharmaceutical composition comprising said hyper immune serum reactive antigen comprising fragment thereof , said pharmaceutical composition further comprising an immunostimulatory substance a peptide containing at least two Lys-Leu-Lys motifs, said composition is a vaccine. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims have been discussed supra. This means that the claims are drawn to a whole multitude of undefined hyperimmune serum reactive antigens

The specification teaches *S. agalactiae* hyper immune serum reactive antigen having the amino acid sequence SEQ.ID.NO:364 and pharmaceutical composition comprising *S. agalactiae* hyper immune serum reactive antigen having the amino acid sequence SEQ.ID.NO:364 , however fails to disclose hyper immune serum reactive antigen comprising fragments of SEQ.ID.NO:364 and pharmaceutical compositions comprising *S. agalactiae* hyper immune serum reactive antigen comprising fragments. Therefore, hyper immune serum reactive antigen comprising fragments of SEQ.ID.NO:364 and the pharmaceutical composition or vaccine comprising hyper immune serum reactive antigen comprising fragments for use in vivo for the treatment of disease can't predictably use said fragments as claimed.

While the disclosure provides guidance how to make the claimed hyper immune serum reactive antigen, SEQ ID NO: 364 comprising the 643 amino acid sequence from *S.*

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agalactiae, the specification fails to disclose hyper immune serum reactive antigen comprising fragments of SEQ ID NO: 364 . Therefore, the use of fragments as claimed (i.e., hyper immune serum reactive antigen comprising fragments of SEQ ID NO: 364) are not yet known or taught by the disclosure.

The specification fails to provide guidance for an isolated hyper immune serum reactive antigen comprising, (open language) fragments of SEQ ID NO: 364 plus unlimited and unknown amino acids that would result in an unknown hyper immune serum reactive antigen comprising fragments without any structure and other identifying characteristics such as function. Thus, hyper immune serum reactive antigen comprising fragments as claimed are broader than the hyperimmune serum reactive antigen comprising the amino acid sequence SEQ.ID.NO: 364 and the specification fail to provide sufficient guidance such that one of ordinary skill in the art can predict a priori what hyper immune serum reactive antigen comprising fragments of SEQ.ID.NO: 364 can be made that will function as contemplated or claimed. Hyper immune serum reactive antigens comprising fragments will function as full length are not routine in the art. The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1)

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the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The specification teaches *S. agalactiae* hyper immune serum reactive antigen having the amino acid sequence SEQ.ID.NO:364 and pharmaceutical composition comprising *S. agalactiae* hyper immune serum reactive antigen having the amino acid sequence SEQ.ID.NO:364, however fails to disclose *S. agalactiae* hyper immune serum reactive antigen comprising fragments of SEQ.ID.NO:364 and pharmaceutical compositions comprising *S. agalactiae* hyper immune serum reactive antigen comprising fragments. The teaching of the specification cannot be extrapolated to enable the scope of the claims because the claims as broadly drawn include hyper immune serum reactive antigens comprising fragments and is acknowledged to be unpredictable because the specification fails to disclose the critical residues that are important for any function or disclose any changes made in an antigen, SEQ.ID.NO: 364 to obtain fragments that can be used for *S. agalactiae* infection. The specification provides no information on the immunogenicity of hyper immune serum reactive antigen comprising fragments or the ability of such fragments to treat or protect or diagnose *S. agalactiae* bacterial infection as contemplated. The specification fails to teach that the claimed fragments are capable of generating a humoral or cellular immune response such that broadly claimed fragments can be used to treat or prevent or diagnose *S. agalactiae* infections. The specification fails to teach any immune response generated by means of hyper immune serum reactive antigen comprising fragments would recognize the full length antigen. It is well recognized in the art, that it is unclear whether undefined fragments derived from a pathogen will elicit protective immunity. Ellis, R.W. (Chapter 29 of "VACCINES" Plotkin, 5.A. et al. (eds)

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published by W. B. Saunders company (Philadelphia) in 1988, especially page 571, 2nd full paragraph] exemplifies this problem in the recitation that "The key to the problem is the identification of that protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies.... and thus protect the host against attack by the pathogen". The specification fails to teach hyper immune serum reactive antigen fragments thereof alone or in combination with immunostimulatory substances in pharmaceutical composition to confer protection from infection, as is requisite of a method of treatment or prevention or diagnosis. In the absence of a teaching of the claimed antigen comprising fragments of SEQ.ID.NO: 364 can generate an immune response and that immune response is effective in diagnosis or prevention or treatment of infection, the specification is not be enabled for claimed antigen comprising fragments of SEQ.ID.NO: 364 : In view of the unpredictability of the art, the lack of teachings of the specification, it would require undue experimentation on the part of the skilled artisan to practice the invention as claimed.

Claim objections/ Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claim 39 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

MPEP: 2173 states that claims must particularly point out and distinctly claim the invention. The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. A secondary purpose is to provide a clear measure of what applicants regard as the invention so that it can be determined whether the claimed invention meets all the criteria for patentability and whether the specification meets the criteria of 35 U.S.C. 112, first paragraph with respect to the claimed invention.

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In claim 39, tables 1A, 1B, 2, 4, 5, 6 and 7 contain several sequences and there is no practical way of defining the invention clearly.

Claim Objections

Claim 38 is objected because it recites non elected sequences ,SEQ.ID.NO as the elected invention is SEQ.ID.NO:364.

Claim Rejections - 35 USC 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 38-44, 45-49 and 53-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Telford et al Accession number ABP28545, publication number WO 200234771-A2 (As this document contains more than 4200 pages, the examiner is sending only accession number and abstract)

Claims are drawn to a pharmaceutical composition comprising at least one hyper immune serum reactive antigen *S. agalactiae* hyper immune serum reactive antigen SEQ ID NO. 364 or fragments thereof and optionally a pharmaceutically-acceptable carrier or excipient said pharmaceutical composition further comprising an immunostimulatory substance.

Telford et al disclose an isolated hyper immune serum reactive antigen comprising (i.e., fragment) fragment and said fragment is 100% identical to the claimed hyper immune serum reactive antigen *S. agalactiae* antigen comprising fragments thereof (see the sequence

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alignment). Thus the prior art read on the claims 38-44 . The teaching of the Telford et al disclose that the pharmaceutical compositions comprise therapeutic amount of peptide fragments (---) in a pharmaceutically acceptable carrier (abstract) and thus it reads on claims 45-46. the same compositions comprises two different hyper immune serum reactive antigen as 643 amino acid sequence comprises different fragments and thus read on claims 47 and 48 . This composition is a vaccine composition as it used for therapeutic or preventive disease and thus meet the limitations of claim 53-54. Further, the art reads on claim 49 as the composition comprise immunostimulatory substance such as adjuvants etc. Thus, the prior art anticipated the claimed invention.

14. Claims 38-44, 45-49 and 53-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Glaser et al Accession number ADV88412 and publication number FR 2824074. Claims are drawn to a pharmaceutical composition comprising at least one hyper immune serum reactive antigen *S. agalactiae* hyper immune serum reactive antigen SEQ ID NO. 364 and optionally a pharmaceutically-acceptable carrier or excipient said pharmaceutical composition further comprising an immunostimulatory substance.

Glaser et al Accession number ADV88412 disclose an isolated hyper immune serum reactive antigen comprising the amino acid sequence SEQ.ID.NO:806 (i.e., fragment) and is 100% identical to the claimed SEQ.ID.NO: 364 (see the sequence alignment). Thus the prior art read on the claims 38-44 . The teaching of the Glaser et al disclose that the pharmaceutical compositions comprise therapeutic amount of peptide SEQ.ID.NO: 806 (English abstract) in a pharmaceutically acceptable carrier and thus read on claims 45-46. the same compositions comprises two different hyper immune serum reactive antigen as 643 amino acid sequence comprises different fragments and thus read on claims 47 and 48 . This composition is a vaccine composition as it used for therapeutic or preventive disease and thus meet the

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limitations of claim 53-54. Further, the art reads on claim 49 as the composition comprise immunostimulatory substance such as adjuvants etc. Thus, the prior art anticipated the claimed invention.

Remarks

15. No claims are allowed.

Relevant Prior Art

16. The prior art made of record and not relied upon in any of the rejections is considered pertinent to Applicants' disclosure:

Wanger et al Infect Immun. 1987 May; 55(5): 1170–1175 analyze the immune response of cows to *Streptococcus agalactiae*. Antibody from the milk of cows immunized (via the superficial inguinal lymph node) with formalinized *S. agalactiae* cells or from the milk of cows with *S. agalactiae* mastitis reacted strongly with a group of high-molecular-weight proteinaceous antigens. The two most predominant antigenic polypeptides in this group had apparent molecular weights of 97,000 and 104,000. Because the data indicated that these two antigens, as well as several minor antigens sometimes observed in the 70- to 100-kilodalton size range, seemed to be different forms of the same protein, we refer to the entire group as Sas97/104. A monoclonal antibody that was reactive with Sas97/104 was derived and was used to purify the antigen by affinity chromatography. Whole-cell and colony blot enzyme-linked immunoassays with either the monoclonal antibody or a polyclonal serum sample raised against the affinity-purified antigen indicated that this antigen (or cross-reactive proteins with higher molecular weights) is present on the *S. agalactiae* strains that were freshly isolated from mastitis cows. However, the antigen was not detected in *S. agalactiae* of human origin, bovine strains of *S. agalactiae* maintained for a prolonged period in the laboratory, or other streptococci.

Moyo et al CLINICAL AND DIAGNOSTIC LABORATORY IMMUNOLOGY, Nov. 2001, Vol. 8, No. 6 p. 1110–111 teach Group B streptococci (GBS) express strain-variable and surface-localized proteins, which are important serotype markers and targets of protective antibodies. These include the c₊ and R4 proteins, one or the other of which is expressed by approximately 75% of clinical GBS isolates. These proteins have been considered vaccine candidates. In this study, the c₊ and R4 proteins were extracted by trypsin digestion of GBS and purified by sequential precipitation with trichloroacetic acid and ammonium sulfate followed by gel filtration chromatography. The proteins were used as antigens in an indirect enzyme-linked immunosorbent assay (ELISA) to measure the levels of c₊- and R4-reactive antibodies in sera from pregnant women from Norway (n = 100) and from Zimbabwe (n = 124). Antibody levels in the Norwegian group of women were significantly higher than in the Zimbabwean group, and a higher proportion of the Norwegian women contained appreciable levels of antibodies against both proteins. The antibodies traversed the placental barrier. With individual sera, a significant

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correlation between the anti-c₁ and anti-R4 antibody levels was observed and each of the two protein antigens effectively competed for human serum antibodies both against itself and against the other antigen. Inhibition ELISA results demonstrated specificity for each of the proteins of immune antibodies raised in rabbits. These results demonstrate that (i) the majority of women of childbearing age have antibodies against c₁ and R4, (ii) the levels of these antibodies differ among pregnant women in different parts of the world, and (iii) the normal human serum antibodies may target a common c₁ and R4 protein site, whereas immune antibodies targeted a different site(s) specific for each protein.

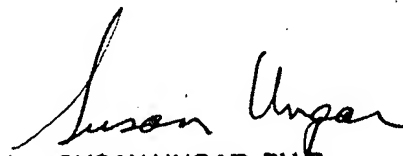
Conclusion

18. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600 or Art Unit 1645 LIE, Victor Barlow whose telephone number is 571-272-0506.



SUSAN UNGAR, PH.D.
PRIMARY EXAMINER



Padma Baskar Ph.D

